

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/JP2004/011864

International filing date (day/month/year)
12.08.2004

Priority date (day/month/year)
12.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61K7/06, A61P17/14, A61K31/22, A61K31/357, C07D317/30, C07D319/06

Applicant
SUCAMPO AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

10/567462

International application No.
PCT/JP2004/011864

1P20Res'd PCT/JP10 07 FEB 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/JP2004/011864

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 9 (industrial applicability)

because:

- ☒ the said international application, or the said claims Nos. 9 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/JP2004/011864

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9,10
	No: Claims	1-8,11-13
Inventive step (IS)	Yes: Claims	
	No: Claims	1-13
Industrial applicability (IA)	Yes: Claims	1-8,10-13
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/JP2004/011864

IAF20 Rec'd PCT/PTO 07 FEB 2006

Re Item III.

Claim 9 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

1 The following documents are referred to in this communication:

- D1 : US 6 353 014 B1 (HELLBERG MARK R ET AL) 5 March 2002 (2002-03-05)
- D2 : US 4 088 775 A (SKUBALLA WERNER ET AL) 9 May 1978 (1978-05-09)
- D3 : EP 0 308 135 A (UENO SEIYAKU OYO KENKYUJO KK) 22 March 1989 (1989-03-22)
- D4 : US 3 962 218 A (VORBRUGGEN HELMUT ET AL) 8 June 1976 (1976-06-08)
- D5: US-B-6 262 1051 (JOHNSTONE MURRAY A) 17 July 2001 (2001-07-17)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses ophthalmic compositions comprising compounds with two heteroatoms at the 15 position (see claim 17). These compositions are suitable for application to the hair.

Document D2 discloses compositions comprising compounds with two heteroatoms at the 15 position (see claim 1). These compositions can be made in a spray form which would make them suitable for application to the hair. (see column 12, lines 12-14).

3 INDEPENDENT CLAIM 11

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 11 is not new in the sense of Article 33(2) PCT.

Documents D1-D4 disclose compounds which fall in the formula (I) of claim 11 of the present application. (see respectively claim 14 of D1, claim 1 of D2, compounds 8 and 9 on pages 13 and 14 of D3, and claims 1,11-22 of D4).

4 DEPENDENT CLAIMS 2-8, 12, 13

Dependent claims 2-8, 12, 13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

5 INDEPENDENT CLAIMS 9,10

5.1 Document D5, which is considered to represent the most relevant state of the art, discloses a method comprising the administration of prostaglandin derivatives for treating alopecia (see claim 1).

From this, the subject-matter of independent claims 9,10 differ in that there are two heteroatoms in the position 15 of the prostaglandin derivatives.

5.1.1 The subject-matter of claims 9,10 is therefore novel (Article 33(2) PCT)

The problem to be solved by the present invention may be regarded as the treatment of alopecia.

5.1.2 The solution to this problem proposed in claim 9 of the present application is considered as not involving an inventive step (Article 33(3) PCT) for the following reasons:

The document D5 is regarded as being the closest prior art to the subject-matter of claim 9, and discloses a method for treating alopecia employing prostaglandin derivatives having a keto group at the 15 position (see column 11, compound 3) from which the subject-matter of claim 9 differs in that the keto group has been converted to an acyclic or cyclic diester group (ketal formation). Such a chemical change comes within the scope of the customary practice followed by persons skilled in the art. Consequently, the subject-matter of claim 9 lacks an inventive step.

5.1.3 The reasoning of claim 9 applies, mutatis mutandis, to the subject matter of the independent claim 10 which therefore is also considered not inventive.

7 INDUSTRIAL APPLICABILITY

For the assessment of the present claim 9 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.